SEPTEMBER 30, 2009 Atty Dkt. No.: P1054US00
USSN: 10/771,383

REMARKS

FORMAL MATTERS

No amendments have been made to the specification, claims or drawings.

REJECTIONS UNDER § 103(A)

The Examiner rejected all of the claims again for allegedly being obvious in view of Lin et al. The Examiner states that the Applicant's previous arguments are not persuasive "because of the open claim language comprising encompasses the scope of the full invention". By this statement the Applicant understands that it is the Examiner's belief that the processes described in Lin et al render the present application obvious. The Applicant disagrees. In order for there to be a prima facie case of obvious all of the elements need to be found in the prior art. The Applicant would like the Examiner to identify the location of step (b) of the claim 1 of the present application in the cited art. Use of the word "comprising" in claim 1 of the present application does not change the nature of step (b) in which it is clear that addition of the atorvastatin sodium salt to an aqueous calcium chloride or calcium acetate solution is essential. The word "comprising" does not affect the nature of this step (b) and hence the Applicant is somewhat puzzled by the Examiner's insistence that the "open claim language comprising" is problematic.

Alternatively, if the Examiner is of the opinion that the word "comprising" of claim 1 of Lin et al. is problematic, then Applicant submits that such an approach is unsuitable on the basis that all other processes, whether or not they were for making atorvastatin or any other compound by any other method would be encompassed by this logic. The word "comprising" as used in claim 1 of Lin et al. does not render obvious a claim to a process comprising all of the same steps and an additional step or a claim with less than all of the steps of claims 1 of Lin et al.. Furthermore, the word "comprising" as set out in claim 1 of Lin et al. does not teach that you must add the atorvastatin sodium salt to the aqueous calcium chloride or calcium acetate solution, as required by claim 1 of the present application.

As recited previously by the applicant, the order of the addition of the salt to the solution, as taught by the present application, provides advantages over the cited art. The Examiner

alleges that there is no evidence of record for these advantages, but fails to explain why the Examples of the application are not sufficient evidence. Applicant submits that Example 1 is a comparative example and may be contrasted with Examples 2 and 3 of the present application in order to provide evidence of record of the advantageous qualities of the present processes. In particular Examples 2 and 3 of the present application (which are representative of processes according to the present invention) clearly show that the combined time required for the filtration and washing steps, when carried out under the same filtration and washing conditions as Example 1 (which is representative of the Lin et al. processes), is reduced by over 50% in both cases when compared to Example 1 and that the moisture content of the damp filter cake of Examples 2 and 3 are significantly less when compared to Example 1. This is clear evidence of record providing evidence of the advantages of the present invention as set out in the description of the present invention. The Examiner is respectfully requested to withdraw the rejection.

CONCLUSION

The pending claims are believed to satisfy all of the criteria for patentability and are in condition for allowance. An early indication of the same is therefore kindly requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided below.

No fees beyond those submitted herewith are believed to be due in connection with this communication. However, the Commissioner is authorized to charge any underpayment of fees associated with this communication under 37 C.F.R. §§ 1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-4648, order number P1054US00.

Respectfully submitted, APOTEX INC.

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